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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,525	12/29/2003	Tae-Woong Koo	043395-0377942	9348

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Pillsbury Winthrop Shaw Pittman LLP
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EXAMINER

POHNERT, STEVEN C

ART UNIT	PAPER NUMBER
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1634

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/748,525	Applicant(s) KOO ET AL.	
	Examiner STEVEN C. POHNERT	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/10/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-10,24,25 and 28-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-10,24,25 and 28-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim status

The instant office action is directed to the response received on 11/10/2009.

Claims 1-2, 5-10, 24-25, 28-48 are pending and under consideration.

Any rejection not specifically reiterated below has been withdrawn.

The 112-2nd rejection of claims 1-2, 5-10, 24-25, 28-48 has been withdrawn in view of the amendment.

The 102 rejections based on Cronin and Han have been withdrawn in view of the amendment to require that a first detectably distinguishable label is used to encode the base information for the first nucleotide of the oligonucleotide.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 2, 6-9, 24-25, 30-32, 37-48 rejected under 35 U.S.C. 103(a) as being unpatentable over Dower et al (US patent 6,140,493 issued Oct 31, 2000).

With regards to claim 1 and 24, Dower is drawn to a method of synthesizing random oligomers with identification tags to screen for desired properties (abstract). Dower teaches the instant method is drawn to a general stochastic method of synthesizing random oligomers of nucleoside which have and identifier that identifies the monomers of the oligomers (column 3, lines 18-40). Dower teaches that one may attach alphanumeric tags to identify each position of oligomers (column 14, line 20-35 and figure 2). Dower position 1 of the oligomers is encoded by a microscopically recognizable (A1, B1, or C1). Dower position 2 of the oligomers is encoded by a microscopically recognizable (A2, B2, or C2). Dower position 3 of the oligomers is encoded by a microscopically recognizable (A3, B3, or C3). Dower teaches the combination of the 9 microscopically recognizable markers allow for the encoding of 27 different oligonucleotide probes. Dower thus teaches a population 27 oligonucleotide probes having 3 bases which are encoded by the use of 9 distinguishable detectable labels.

With regards to claim 2 and 25, Dower teaches each detectable label is present one, which is less than 4 times.

With regards to claims 6 and 29 teaches the oligomer sequences are typically less than 20 residues and in many cases 10-12 residues (column 10, lines 5-15).

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With regards to claim 9 and 33, Dower teaches the tag can be a fluorescent compound (column 4, lines 64-67).

With regards to claim 7,8, 31-32, Dower teaches the use of fluorescein in the probes (column 25, lines 1-9)). As claim 8 depends from claim 7, the claims teach that fluorescein is a Raman label. Thus Dower teaches Raman labels.

With regards to claim 30, the Dower teaches the population of oligonucleotide probes comprise all 27 possible combinations of 3 nucleotides.

With regards to claims 37 and 38, Dower teaches each of detectable tags encode the nucleotide at a specific position of the polynucleotide.

With regards to claim 39 and 55, Dower teaches the oligonucleotides are single stranded.

With regards to claim 40 and 45 Dower teaches the sequences can be cleaved from a solid support (column 12. lines 21-25).

With regards to claim 41- 43, 46-48, Dower teaches each label is attached to the monomers (see figure2). Dower thus teaches each labeled oligonucleotide comprises two or more linkers as each oligonucleotide has at least 3 labels.

Dower does not teach the synthesis of oligonucleotide probes or teach oligonucleotide is of identical 10 to 50 nucleotides in length. Dower does not specifically teach a reaction mixture comprising an isolated population of labeled probes and a target nucleic acid.

However, Dower teaches nucleoside can be use as monomers (column 3, lines 18-40). Further Dower teaches that oligomers can be up to 20 residues in length.

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Dower teaches specific beads with oligomers attached can be isolated in a receptor screening assay (column 19, lines 5-10).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to make different labeled oligonucleotide probes of 10 -20 nucleotide in lengths as Dower suggests that oligomers can be made of nucleoside monomers and that the monomers can be up to 20 nucleotides in length. It would further have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the oligonucleotide probes in a reaction mixture with a target nucleic acid. The artisan would be motivated as Dower suggests the beads with oligomers attached can be used to screen the library for specific properties or receptor screening assays. The hybridization of a target nucleic acid (receptor) with its complement (oligonucleotide probe) can be considered as a receptor screening as it is identifying sequences that specifically bind to the target nucleic acid. It is also screening the labeled oligonucleotide probe for a specific property, the ability to hybridize with its complement. The artisan would be motivated as Dower suggests these methods. The artisan would have a reasonable expectation of success as Dower suggests such probes.

4. Claims 5, 9, 10, 28, 34, and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dower et al (US patent 6,140,493 issued Oct 31, 2000) as applied to claims 1, 2, 6-9, 24-25, 30-32, 37-48 above, and further in view of Bawendi et al (US PG PUB 2002/0160412, filed 9/24/1998) and Han et al (Nature Biotechnology (2001) volume 19, pages 631-635).

This rejection is presented to claim 9 as it is drawn to quantum dots.

The teachings of Dower are set forth above.

Dower does not teach the each nanotag has an intensity reference signal molecule (claims 5 and 28). Dower does not teach the signal molecules are a series of nanotags (claims 10 and 34). Dower does not teach the location of a peak in a response spectrum indicates the presence of a particular labeled oligonucleotide probe, while the intensity of the peak is proportional to the number of a particular oligonucleotide probe (claim 35 and 36).

However, Bawendi teaches quantum dots can be used for identification of reaction history of the synthesis of a combinatorial library (0060). Bawendi teaches that the use of quantum dots provide for distinct non-overlapping resonance capable of detection of different intensities enabling the use of binary or higher encoding systems (0062). Bawendi teaches, "The advantages of the quantum dots, namely the ability to observe discrete optical transitions at a plurality of intensities, provides a powerful and dense encoding scheme that can be employed in a variety of disciplines. In general, one or more quantum dots may act as a barcode, wherein each of the one or more quantum dots produces a distinct emissions spectrum" (0049).

With regards to claim 10, Han teaches the use of quantum dots, which are "zinc sulfide-capped cadmium selenide nanocrystals" (see abstract 2nd line). Han thus teaches the use of nanotags.

With regards to claim 5 and 28, Han et al teaches each labeled oligonucleotide probe is labeled with F by binding of the target nucleic acid (see figure 5). Han thus

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teaches a reaction mixture with a target polynucleotide and a labeled probe, wherein each signal molecule has an intensity reference signal.

With regards to claims 35 and 36, Han teaches the analyte peak in figure 5 indicates the presence of the oligonucleotide hybridized to the analyte and the intensity of the peaks indicates if probe number 2, 3 or 4 is hybridized to the analytes (see figure 5).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the quantum dots and labeled target nucleic acids of Han and Bawendi as the identifier tag in the probe collections of Dower. The artisan would be motivated as Bawendi teaches quantum dots have improved properties over other labels. The artisan would be motivated to use labeled target nucleic acids as Han demonstrates it allows the artisan to confirm the presence of the target nucleic acid in a hybridization complex with a specific labeled oligonucleotide probe of the population by detection of the reference intensity in conjunction with the identifying intensities of the quantum dots. The artisan would have a reasonable expectation of success as the artisan is merely replacing the method of labeling combinatorial library synthesis taught by the quantum dots taught by Han and Bawendi as suggested by Bawendi for encoding synthesis steps of a combinatorial library.

Response to arguments

This is a new ground of rejection necessitated by amendment.

Summary

No claims are allowed over prior art cited.

Conclusions

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEVEN C. POHNERT whose telephone number is (571)272-3803. The examiner can normally be reached on Monday-Friday 6:30-4:00, every second Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steven C Pohnert/
Examiner, Art Unit 1634

Steven Pohnert